TÜV Rheinland PTL

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Precisely Right.

ISO 17025 QA Accreditation Process

Bindhu Raghuraman
TUV Rheinland PTL

Quality Management System

- A set of interrelated or interacting elements that organizations use to direct and control how quality policies are implemented and quality objectives are achieved (ISO9000:2005)
- Consists of policies, procedures and instructions
- Does not include people

The “tion” Words

Registration

- Procedure by which a registration body indicates relevant characteristics of a product, process or service, or particulars of a body or person, on an appropriate publicly available list (ISO/IEC Guide 2)
- Example: Using ISO9001:2000
- Formal recognition of an organization’s management system
- Registration does not certify or guarantee the quality of products or service for compliance with specific technical specifications

Source: A2LA

The “tion” Words

Accreditation

- Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks (ISO/IEC Guide 2)
- Example: Using ISO/IEC 17025:2005
- Accreditation is having a management system and demonstrating competency

Laboratory Accreditation

- Formal recognition that a testing or calibration laboratory is competent to carry out specific tests or calibrations

Source: A2LA

The “tion” Words

Difference between registration and accreditation

- Generic vs specific
- Competence

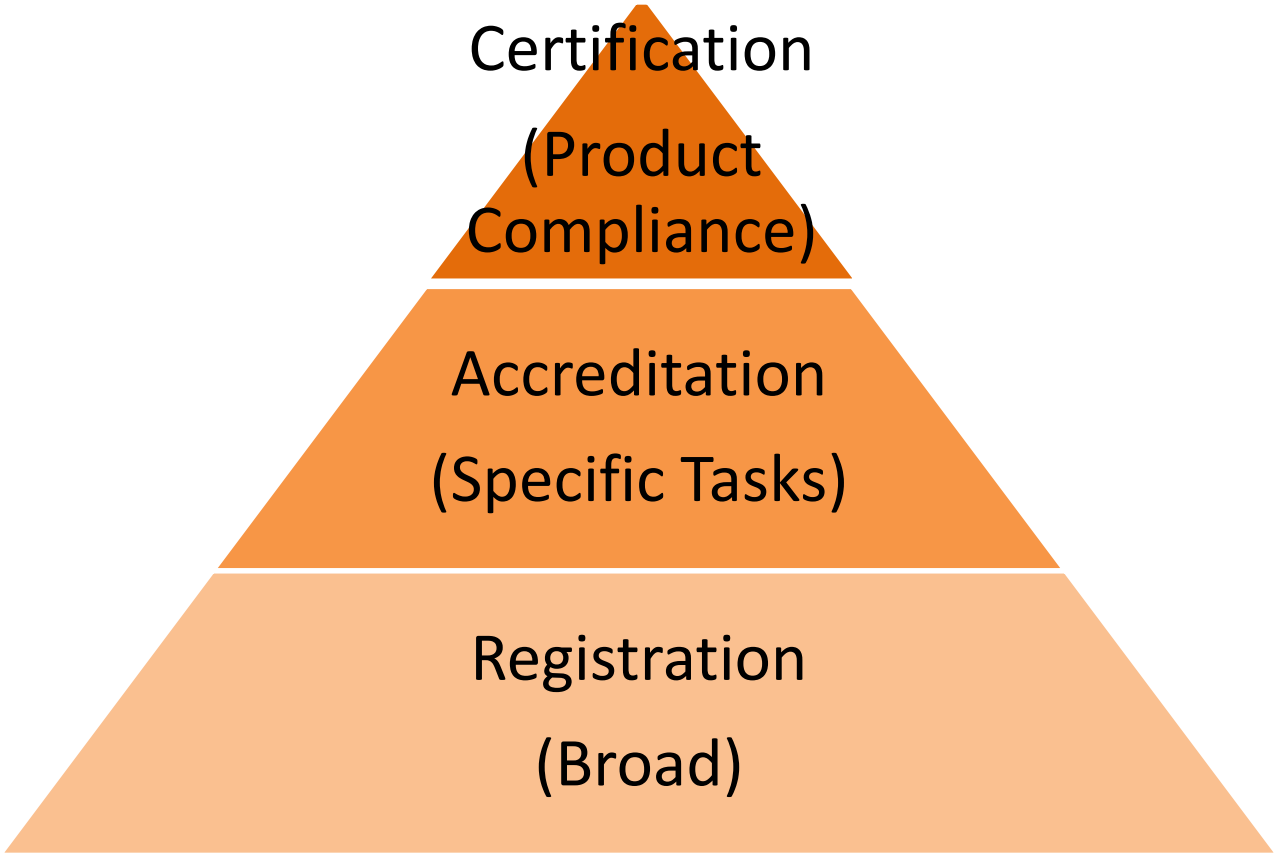
The “tion” Words

Certification

- Procedure by which a third party gives written assurance (certificate of conformity) that a product, process or service confirms to specified requirements (ISO/IEC Guide 2)
- Example: UL and TUV certifications
- Laboratories are usually not certified but accredited

Source: A2LA

Conformity Assessment Hierarchy



Source: A2LA

Accreditation Hierarchy

International Laboratory Accreditation Cooperation (ILAC):
Establishes standards and requirements for accreditation
Recognizes Regional Accreditation Groups

Regional Accreditation Groups (Example: EA, APLAC, IAAC)
Recognizes accreditation bodies through Mutual Recognition Agreements using ISO/IEC 17011

Accreditation Bodies (Example: A2LA, NVLAP)
Follow ISO/IEC 17011
Accredit Laboratories using ISO/IEC 17025:2005

Laboratories (Testing and Calibration)
Follow ISO/IEC 17025:2005
Test or calibrate customer samples, products or materials

Customers
Submit products to laboratories to be tested or calibrated
Follow customer specifications

Source: A2LA

ISO/IEC 17025:2005 - Scope

- Specifies general requirements for the competence to carry out tests or calibrations including sampling
- Applicable to all organizations performing tests and/or calibrations including first, second and third party laboratories
- Used by laboratories in developing their management system for quality, administrative and technical operations
- Meeting the requirements of this standard also implies meeting the requirements of ISO 9001

Management Requirements of ISO/IEC 17025

- Organization
- Management System
- Document Control
- Review of requests, tenders and contracts
- Sub-contracting of tests
- Purchasing services and supplies
- Service to customers
- Complaints
- Control of non-confirming work
- Improvement
- Corrective and preventive action
- Control of records
- Internal Audit
- Management Review

Technical Requirements of ISO/IEC 17025

- Personnel
- Accommodation/environment conditions
- Test methods and method validation
- Equipment
- Measurement traceability
- Sampling
- Handling of test items (samples)
- Assuring the quality of test results
- Reporting the results

Management Requirements: Organization

First party conformity assessment activity:

Conformity assessment activity that is performed by the person or organization that provides the object [ISO 17000]

Second Party Conformity assessment activity:

Conformity assessment activity that is performed by the person organization that has a user interest in the object [ISO 17000]

Third party Conformity assessment activity:

Conformity assessment activity that is performed by a person, or body that is independent of the person or organization that provides the object and of the end user interests in that object [ISO 17000]

Management Requirements: Organization

- Legal entity
- Meet the requirements of accrediting body and customer
- Ensure no conflict of interest for key personnel
- Managerial and technical personnel free from undue pressure and adequately resourced
- Management structure and job descriptions
- Technical management and quality manager
- Deputies for key managerial posts

Management Requirements: Management System

Documents

- Quality manual
- Quality Policies
- Quality policy statement
- Roles of key personnel
- Structure of documents

Related documentation (part of quality manual)

- Standard test procedures
- Training procedures
- Equipment and calibration procedures

Benefits

- Minimizes misconceptions
- Standardizes procedures
- Encourages continuous improvement

Management Requirements: Document and Record Control

Document control

- Control of internal and external documents
- Review and approval of documents
- Master and distribution lists
- Unique identification
- Document changes

Record control

- Procedure for identification, collection, indexing, access and storage
- Records legible, readily retrievable, stored in suitable environment
- Secure and in confidence
- Protection and backup

Management Requirements: Customer Service and Complaints

Customer Service

- Allow customers to clarify their request
- Allow monitoring or auditing the performance of the laboratory while protecting confidentiality of other customers
- Seek feedback (positive and negative) and analyze data

Handling Complaints

- Policy and procedure for receiving and resolving complaints
- Records of all complaints including investigations and corrective actions

Management Requirements: Control of Non-Confirming Work

Policy and procedure for non-conforming testing work including

- Responsibilities and authorities for management defined
- Evaluation of significance
- Remedial actions
- Recalling non-conforming work released to customers
- Responsibility for resuming work

Management Requirements: Corrective and Preventive Action

Corrective Action

- Policies, procedures and authorities for non-conforming work and departure from policies and procedures
- Identification of problem
- Root-cause analysis
- Selection and implementation of corrective action
- Monitoring of corrective action
- Additional audits may be necessary

Preventive Action

- Opportunity for improvement
- Identify potential opportunities for non-conformities
- Development of action plans
- Implementation of the action plans

Management Requirements: Internal Audit and Management Review

Internal Audit

- Each element of the quality system and each section audited
- Checking for evidence against requirement
- Trained and qualified personnel; independent
- Pre-determined schedule
- Confirm compliance with requirements of the Management System and ISO/IEC 17025
- Records of the audit and corrective actions maintained
- Done at least once a year

Management Review

- Evaluate suitability and effectiveness of policies and procedures
- Discuss findings of internal audit, external assessment, customer complaints, corrective and preventive action and possible improvements to the existing system
- Record findings and actions
- Pre-determined schedule
- Done at least once a year

Technical Requirements: Personnel

- Ensure competency of personnel
- Appropriate supervision for all personnel under training
- Formulate goals with respect to education, training and skills
- Policies and procedures for identification of training needs and providing training
- Current job descriptions
- Records of all technical personnel including training, competency data and date of authorization
- Competency of contract employees and supervision of work as per management system

Technical Requirements: Equipment

- Laboratory furnished with all necessary equipment
- Equipment and software capable of producing accurate results
- Up-to-date instructions readily available
- Training for all personnel handling equipments
- Unique identification and records of each equipment maintained
- Accredited (traceable)calibration necessary on a pre-determined schedule

Technical requirements: Test Methods and Method Validation

Test Methods

- Appropriate methods used on all aspects of test
- Instructions available for operation of test equipment
- Test methods and procedures maintained up-to-date
- Deviations documented, justified, authorized and accepted by client
- Non-standard methods accepted by client and validated
- Validation procedures, records and statement of fitness be readily available

Method Validation

- Validate non-standard methods, laboratory developed methods, standard methods used outside scope, modifications of standard methods
- Extent of validation: as necessary to meet the needs of the given application or fit for “the intended use”

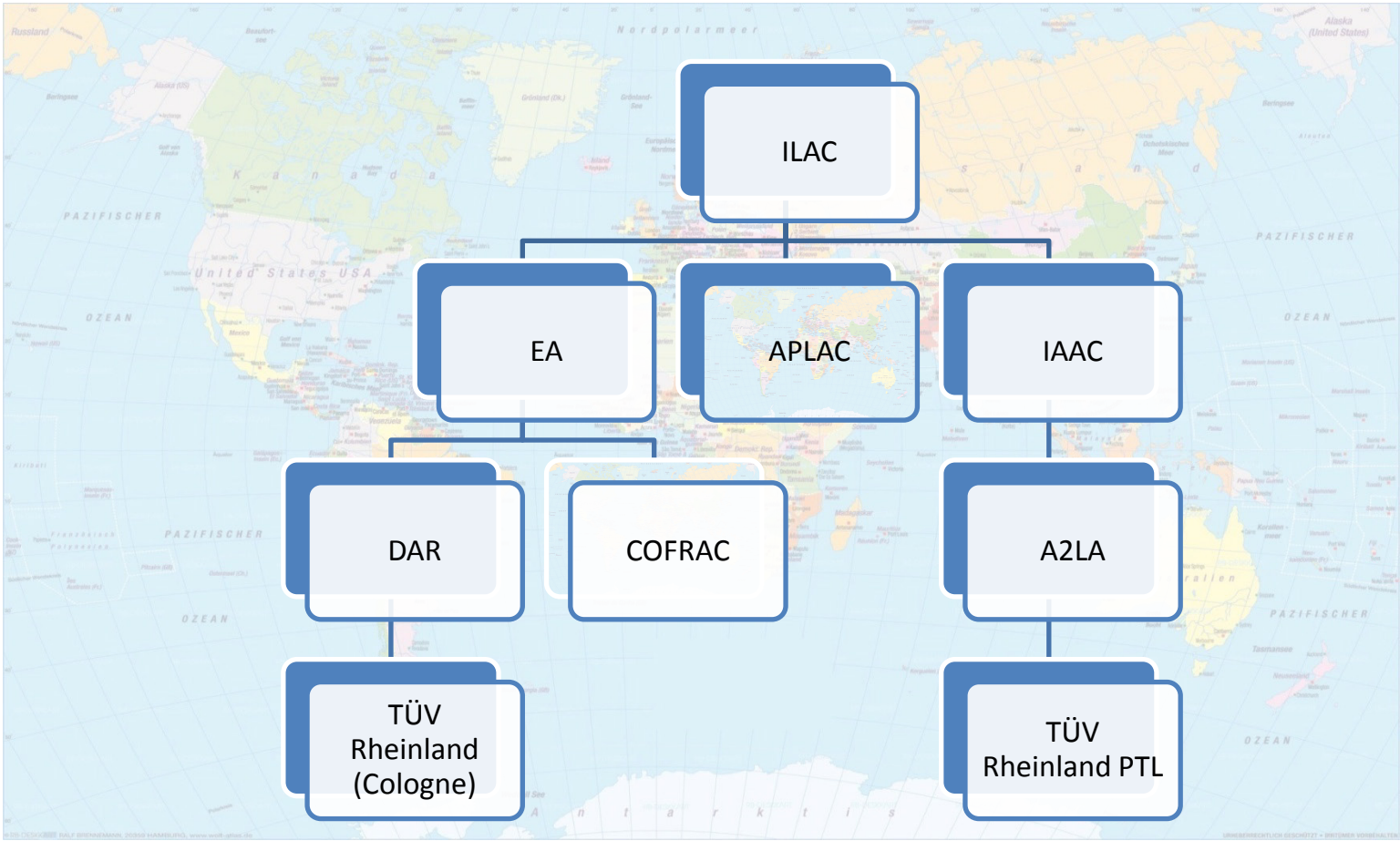
Technical Requirements: Assuring Quality of Test Results

- Quality control procedures to be documented and implemented
- Data recorded in a way where trends are detectable, and can be easily reviewed using statistical techniques
- Monitoring validity of results using planed and documented procedures such as internal QC schemes, proficiency testing etc.
- Quality control data analyzed and compared to acceptable range

Why get accredited?

- Establishes minimum competency standards
- Identifies laboratory's specific competencies
- Documents non-conformities
- Improves performance
- Enables continuous improvement
- Meets regulatory/procurement requirements
- Assures acceptance of data
- Breaks down barriers to international trade

What it Means to Customers-An Example



What it Means to Customers

- World-wide recognition of data
- Legitimate
- Assurance to meet quality requirements of consumers
- Reduced risk

Thank You!

Questions?